REMARKS

Status of the Claims

Claims have been canceled and amended in response to the section 112 rejections, these amendments and cancellations are detailed below.

Rejections Under 35 USC 112

Claims 8-17, 19, 38, 40, 59, 61, and 62 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The examiner states:

> The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.
>
> The following is new matter: the actuator comprises a hydraulic pump (claim 8); the actuator has a visualization window (claim 9); the visualization window has means for measuring the amount of viscous material being delivered (claim 10, 11, 15, and 16); the delivery tube is noncompliant (claim 12 and 38); the container is adapted to hold at least 3 cc of viscous cement (claim 13; it is noted that this claim language would include containers adapted to hold any amount greater then 3 cc which is not supported originally filed specification); the container comprises a visualization window (claim 14); the container is made from a noncompliant material (claim 17); the amount of fluid in the vessel is greater then the amount of viscous [bone cement] to be delivered (claim 19); determining the amount of viscous material delivered from a visualization window (claim 40); cooling said bone cement in a manner sufficient to delay it solidification (claim 59); delivering 10 cc of bone cement to a bone (claim 61); and not replacing a cement chamber during a single medical procedure (claim 37).
>
> Therefore, the date of invention of claims 8-17, 19, 38, 40, 59, 61, and 62 is the filing date of said claims, which is 23 December 2005, and will be considered as such for further examination.

Claims 10, 11, 12, 15, 16, and 19 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The examiner states:

a. Claim 10 recites the limitation "the visualization window" in line 1-2. There is insufficient antecedent basis for this limitation in the claim.

b. Claim 11 recites the limitation "the means for measuring" in line 1-2. There is insufficient antecedent basis for this limitation in the claim.

c. Claim 12 recites the limitation "the delivery tube" in line 1-2. There is insufficient antecedent basis for this limitation in the claim.

d. Claim 15 recites the limitation "the visualization window" in line 1-2. There is insufficient antecedent basis for this limitation in the claim.

e. Claim 16 recites the limitation "the means for measuring" in line 1-2. There is insufficient antecedent basis for this limitation in the claim.

f. Claim 19 recites the limitation "the vessel" in line 1-2. There is insufficient antecedent basis for this limitation in the claim.

Applicant has addressed these issues, with no prejudice intended, as follows:

Claim 7 – canceled;

Claim 8 – amended to conform to paragraph 44 of the specification;

Claims 9 to 11 – canceled;

Claim 12 – amended to conform to paragraph 50 of the specification;

Claims 13-17 – canceled;

Claim 19 – canceled;

Claim 20 – amended to conform to paragraph 53 of the specification;

Claim 38 – amended to conform to paragraph 50 of the specification;

Claim 40 – canceled;

Claim 59 – amended to conform to paragraph 53 of the specification;

Claim 61 – no action, this appears to be supported in paragraph 57 of the specification; and

Claim 62 – canceled.

Applicant believes that each objection stated by the Examiner has been addressed.

Rejections Under 35 USC 102(e)

Claims 8-17, 19, 38, 40, 59, 61, and 62 are rejected under 35 U.S.C. 102(e) as being clearly anticipated by US 2005/0070915 to Mazzuca et al. The Examiner states:

> It is noted that said claims have a date of invention of 23 December 2005.
>
> Mazzuca discloses a method of delivering a viscous bone cement material under fluoroscopy to a site in a patient (see Abstract), comprising: providing a delivery device (see Fig. 2) having: a container 60 containing a viscous bone cement (see ¶ 50) prior to the bone cement having set, the container having an exit port; an actuator 40 having an actuator vessel, the actuator vessel containing an incompressible fluid; and a hydraulic coupling tube 15 connecting the actuator vessel to the container; locating the container with respect to the patient so that cement leaving the container through the exit port is delivered to a desired injection site within the patient (see ¶ 56); and while at least a portion of the patient is subjected to fluoroscopic imaging, actuating the actuator from a location outside a field of fluoroscopic imaging to hydraulically drive a flow of viscous bone cement through the exit port to the desired injection site within the patient (see claim 53). Mazzuca further discloses the additional claim limitations (see claims 1-62)

Given the Applicant's addressing of the written description issues, the claims are entitled to the PCT filing date, and Mazzuca is not prior art.

Rejections Under 35 USC 103(a)

Claims 7-9, 12, 13, 20, 36-40, and 78 are rejected under 35 U.S.C. 103(a) as being unpatentable over "Percutaneous Vertebroplasty Guided by a Combination of CT and Fluoroscopy" by Gangi et al. (cited by applicant; hereinafter "Gangi") in view of US 4,250,887 to Dardik et al. (hereinafter "Dardik"). The Examiner states:

> Concerning claims 37 and 78: Gangi discloses a method of delivering a viscous bone cement material under fluoroscopy to a site in a patient (see *Technique of Injection* section), comprising: providing a delivery device/tube having: a container (i.e. a syringe) containing a viscous bone cement (see page 82, top of the second column) prior to the bone cement having set, the container having an exit port; locating the container with respect to the patient so that cement leaving the container through the exit port is delivered to a desired injection site within the patient (see *Technique of Injection* section); and while at least a portion of the patient is subjected to fluoroscopic imaging, driving a flow of viscous bone cement through the exit port to the desired injection site within the patient (see page 84, column 2, ¶ 1-3).
>
> Gangi does not specifically discloses an actuator having an actuator vessel, the actuator vessel containing an incompressible fluid; and a hydraulic coupling tube connecting the actuator vessel to the container; and actuating the actuator from a location outside a field of fluoroscopic imaging to hydraulically drive the flow.
>
> Dardik however suggests a method for delivering a viscous material (col. 3, I.64) under a radiation field 14 and capable of delivering a viscous material, namely bone cement (naturally follows from similar structure to applicant), to a site in a patient comprising the steps of: providing an actuator 22 having an actuator vessel, the actuator vessel containing an incompressible fluid 35; and a hydraulic coupling tube 33 connecting the actuator vessel to a container 25; and actuating the actuator from a location outside a field of radiation to hydraulically drive the flow of the viscous material from the container (Fig. 1; col. 2, I. 61 to col. 3, I. 15). Dardik suggests this method in order to reduce the radiation exposure to the surgeon (Abstract).
>
> It would have been obvious to someone of ordinary skill in the art at the time of the invention to add the actuator, hydraulic coupling tube and actuation step of Dardik to the method of Gangi in order to reduce the radiation exposure of the surgeon. The entire modified device of Gangi, in view of Dardik, can be considered a delivery tube in the sense that applicant's entire device can be considered a delivery tube.
>
> Concerning claims 7-9, 12, 13, 20, 36 and 38-40: the delivery tube 33 of Dardik is flexible and noncompliant (col. 5, II. 15-20); a linear actuator 22 (Dardik) is involved; determining the amount delivered can be made from a visualization window 20 (Dardik; col. 5, II. 3-7); a separator (26 and 38 of Dardik); cannula (see *Technique of Injection* of Gangi).

The rejection now made is very similar to the rejection made in the previous office action. There, US 6,676,664 to Al-Assir, a reference that used a syringe with a threaded driver, was combined with Dardik to make out an obviousness rejection. Here, Al-Assir has been replaced with Gangi, a reference that uses a syringe with a pressure regulator. Substantively,

there is no difference Al-Assir and Gangi other than a change in the manner of operating the syringe. Accordingly, the descriptions below mirror those from the previous response to office action – including that Applicant still relies on the teaching of Al-Assir for the proposition that a person of ordinary skill would not combine the features of Dardik into a cement injector as Dardik would not be expected to work for that purpose.

Background and Review of the References Cited

Dardik provides a system for the remote dispensing of angiographic dye, while maintaining surgeon "feel" while dispensing:

> The present invention provides a system whereby a surgeon can manually, ***with conventional force and feel,*** cause injection of a radiopaque dye during angiography . . . [Col. 2, lines 52-54.]

Dardik further states that in a "preferred embodiment" (in fact, it is the only embodiment, and thus the only disclosure on this topic in Dardik), Dardik uses as his driving fluid:

> a fluid such as water or oil, which might have a ***density and viscosity generally similar to that of the radiopaque injectate.*** [Col. 2, lines 63 to 65]

There are three results from constructing the angeographic dye injector in the manner described by Dardick: (1) the surgeon maintains the "feel" of injecting the dye, even at a distance; (2) the dye is injected at the same rate that the surgeon works the remote plunger; and (3) the device can be made from standard tubing and syringes:

> With an apparatus as described above, ***the drive syringe and plunger are not only visually familiar to the surgeon, but they are and feel identical to the conventional injectate syringe.*** Modifications may be made if necessary in the dimensions of the drive and driven syringes and intermediate hose filled with fluid, to be sure they ***simulate closely the feel of direct manual injection*** of radiopaque dye, in regard to the mass and viscosity of the dye and the force to discharge same. [Col. 3, lines 16-24.] . . . From this position the surgeon can observe both the area of vascular reconstruction and the coupled syringes; at the same time he has the ***personal control by virtue of the familiar, manual "feel" of the syringe and***

> ***plunger, of the fluid flow and/or resistance to the flow.*** [Col. 5, lines 3 to 8.]
>
> * * *
>
> ***[T]he driven plunger,*** when moved axially, ***will drive the injectate plunger essentially the same distance and at the same rate*** in an ideal hydraulic system. [Col. 3, lines 11-14.]
>
> * * *
>
> Not only does this new invention provide an apparatus that allows "manual" injection from a remote and radiation-safe location, it is extremely simple to use and inexpensive to manufacture; ***even standard syringes and tubing can be used*** . . . [Col. 3, lines 25-30.]

The system of Dardik will not work with a viscous bone cement. The Al-Assir paper cited by the Examiner ("Percutaneous Vertebroplasty: A Special Syringe for Cement Injection," 21 Am. J. Neuroradiol. 159-161 (Jan. 2000)) puts this most directly in its Summary:

> Summary: Percutaneous vertebroplasty is an effective treatment for many focal vertebral lesions. Methyl methacrylate is too viscous to be handled without difficulty in the conventional way because injection time is short. The operator is left with little time and must fumble with multiple syringes. We describe a special screw-system syringe that decreases the effort needed to inject the cement. In addition, it can standardize the injection pressures and control the injected volume because the threaded plunger affords greater control of injection pressure and volume delivered than does the conventional method.

The Al-Assir patent cited by the Examiner in the previous rejection echoes this theme, noting that "[t]he injection of cementing biomaterials is customarily carried out conventionally with standard syringes . . ." but, "the force to be applied to the plunger needs to be considerable." In other words, the hydraulic fluid delivery system of Dardik, which uses a hydraulic driver in which the driving fluid is similar in viscosity to the delivered fluid, that employs conventional syringes does not work well with bone cement. Al-Assir thus sets out to "improve the methods for injecting hardenable masses in vertebroplastia by facilitating the loading of the biomaterial into the interior of an injector device having special features, making it possible to work with

greater injection pressure and to obtain a greater capacity of adjustment thereof . . ." Al-Assir's goal is not to improve upon Dardik, but to replace it entirely with a system that handles higher pressures and larger volumes.

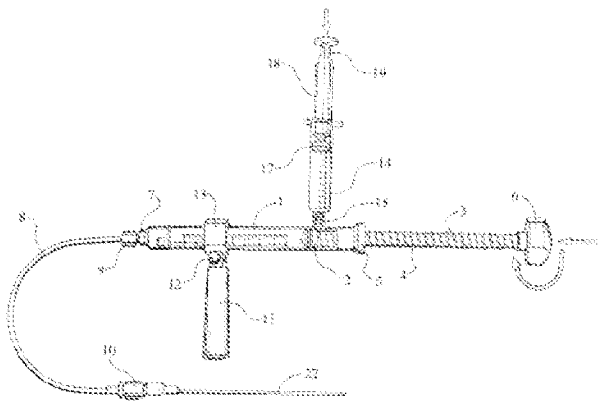
U.S. 6,383,190 to Preissman, also of record in this case, makes this point even more strongly, noting the desirability of high viscosity cements and the many problems involved with injecting them through conventional syringes:

> A viscous or paste-like consistency of PMMA is generally believed to be most advantageous for performing percutaneous vertebroplasty. Such a consistency insures that the implant material stays in place much better than a less viscous, more liquid material. Leakage or seepage of PMMA from the vertebral implant site can cause a host of complications some of which can be very serious and even result in death. For example, Weil et al. reported cases of sciatica and difficulty in swallowing which were related to focal cement leakage, Radiology 1996; Vol 199, No. 1, 241-247. A leak toward the distal veins poses an even more serious risk, since this can cause a pulmonary embolism which is often fatal.
>
> * * *
>
> Because in general, 10 cc syringes are only capable of generating pressures of about 100-150 psi, this places a limitation on the viscosity of the PMMA that can be effectively "pushed through" the syringe and cannula and fully delivered to the implant site. Of course, the use of a small barrel syringe, e.g., a 1 cc syringe, enables the user to generate higher driving pressures. For example, pressures of 1000 psi and possibly as high as 1200-1500 psi (depending upon the strength of the user and the technique) may be generated using a 1 cc syringe. A serious limitation with the use of a 1 cc syringe, however, is that it will not hold a large enough volume to complete the procedure in one step or "load" and must be reloaded several times to complete the procedure, since, on average, about 3.5 cc of implant material per side of the vertebral body are required for an implantation procedure. This makes the procedure more complicated with more steps, and more risky in that the polymerization of the implant material causes it to become increasingly more viscous during the additional time required for reloading. Another problem with a 1 cc syringe is lack of control, as high pressures are generated in a "spike-like" response time and are not continuously controllable.

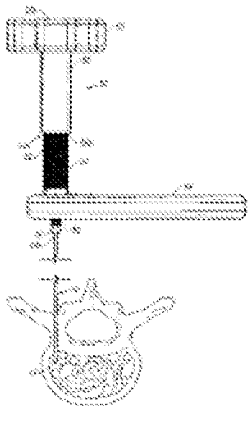
* * *

> Thus, there is a need for a high pressure applicator that has enough storage capacity to perform a complete implantation procedure without having to reload the device in the midst of the procedure, and which is consistently controllable, for an even, constant application of pressure during delivery of the entirety of the implant material. [Col. 1, line 63 to col. 2, line 48.]

Not surprisingly, Al-Assir and Preissman both address these problems with devices that are completely different from, and incompatible with, Dardik:



Al-Assir



Preissman

Both Al-Assir and Preissman provide direct, mechanically-advantaged of bone cement through an elongated tube and/or needle. According to both, this is how one injects viscous bone cement – not using the standard syringes of Dardik.

The Gangi reference discloses even less about how the cement is injected than these other references. Gangi notes that a "10 to 12-gauge trocar needle . . . was introduced into the vertebral body." The actual injection is performed under fluoroscopy, and "[f]our to 8 mL of acrylic glue were injected using a 2-mL Luer Lock syringe mounted on a pressure regulator (Meadox, Oakland, Calif) to facilitate the injection of this viscous mixture." The use of a pressure regulator is the antithesis of the Dardik reference which is specifically engineered to maintain the surgeons "feel" for the injection. Presumably, Gangi needed the pressure regulator

for the reason stated – that the cement was too difficult to inject without the pressure regulator to facilitate it.

Response to Obviousness Rejection

The rejection of independent bone-cement claims 37 and 78 (now, all of the claims recite bone cement) begins with Gangi as the primary reference. As noted by the Examiner, Gangi lacks "an actuator vessel, the actuator vessel containing an incompressible fluid: and a hydraulic coupling tube connecting the actuator vessel to the container; and actuating the actuator from a location outside a flied of fluoroscopic imaging to hydraulically drive the flow." According to the rejection, Gangi delivers a viscous bone cement under fluoroscopic guidance – and that it would have been obvious to someone of ordinary skill in the art at the time of the invention to substitute the steps and apparatus of Dardik et al. into the method of Gangi in order to reduce exposure of the surgeon.

First, the purported obviousness rationale (and the description of Gangi), does not square with the references. Gangi does acknowledge the use of fluoroscopic imaging during delivery of bone cement – but Gangi does not specifically addresses the issue of reducing exposure of the surgeon to the X-rays. Other references, however, such as Al-Assir, specifically describe how to solve the problem of reducing the exposure of the surgeon to X-rays – it is a different solution to the problem, a solution that Gangi seems also to employ. According to Al-Assir:

> A. Puncture and Access:
>
> * * *
>
> The ***use of the long stylet also makes it possible to keep the operator's hands away from the area subjected to ionizing rays (X-rays)***, if this technology is used during the procedure. In these circumstances, the irradiation which the hands may receive during the manipulation of the puncture equipment is reduced.
>
> B. Use of the High Pressure Flexible Tube:
>
> ***This makes it possible to keep the operator's hands away from the irradiated area.*** Moreover, the movements of the operator's hands are not transmitted to the needle, so that accidental displacements of the latter are avoided. [Col. 3, lines 14-34.]

* * *

> Moreover, owing to the arrangement of the tubular member capable of functioning at high pressure, ***the surgeon's hands can remain substantially separated from the direct site of the intervention, thus avoiding excessive exposure to the radiation of the X-ray apparatus*** used for locating the site of the operation. [Col.5, lines 16-21.]

Al-Assir already addresses the issue of reducing the radiation exposure to the surgeon, and does so in a different way than Dardik – in particular, Al-Assir uses the length of the high pressure tubing and stylet to move the move the surgeon away from the ionizing radiation. Gangi uses a similar stylet, and presumably (we have to presume because Gangi is silent) keeps the syringe outside of the fluoro-field, or otherwise operates the pressure regulator in a way that keeps the surgeon's hands outside the field.

The rationale for modifying Gangi stated in the rejection is thus a nullity as the rationale is directly contrary to the art. In order to make out an obvious rejection, the Examiner must provide clear reasons why the person of ordinary skill would make the leap from the prior art to the claims. *See In re Kahn*, 441 F.3d 977, 988 (CA Fed. 2006) ("[R]ejections on obviousness grounds cannot be sustained by mere conclusory statements; instead, there ***must be some articulated reasoning with some rational underpinning*** to support the legal conclusion of obviousness") (emphasis added). Without such rational underpinning, the Examiner easily fall prey to improper hindsight reasoning:

> A factfinder should be aware, of course, of the distortion caused by hindsight bias and must be cautious of arguments reliant upon *ex post* reasoning. *See Graham*, 383 U.S., at 36, 86 S. Ct. 684, 15 L. Ed. 2d 545 (warning against a "temptation to read into the prior art the teachings of the invention in issue" and instructing courts to "'guard against slipping into the use of hindsight'".) *KSR Int'l Co. v. Teleflex Inc.*, 127 S.Ct. 1727, 1742 (Apr. 30, 2007).

Here, where the rational underpinning for the obviousness conclusion fails when compared to the reference, there is in fact no rational underpinning for the combination and a proper obviousness rejection cannot be maintained.

In addition, Al-Assir expressly says that conventional syringes such as those used by Dardik (and Dardik believes that it is an advantage to use them) will not work with viscous bone cement (as explained in detail above) – Gangi only uses them with a pressure regulator. Modifying Gangi by adding the proposed features of Dardik would expressly render Gangi incapable of performing its stated purpose of delivering viscous bone cement. According to MPEP § 2143.01(V), "[i]f [the] proposed modification would render the prior art invention being modified unsatisfactory for its intended purpose, then there is no suggestion or motivation to make the propose modification" (citation omitted). Further, in accordance with MPEP § 2143.01(VI), "[i]f the proposed modification or combination of the prior art would change the principle of operation of the prior art invention being modified, then the teachings of the references are not sufficient to render the claims prima facie obvious" (citation omitted). For this additional reason, the obviousness rejection should not be maintained.

By replacing Al-Assir (which discusses extensively the problems of delivering viscous bone cement under imaging) with Gangi, which discloses less, the Examiner cannot change the teaching in the art. Dardik is still not adaptable to delivering viscous bone cement for all of the reasons stated in the art.

Claims 50 and 51 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gangi in view of Dardik as applied to claim 37 above and further in view of US 5,431,654 to Nic (hereinafter "Nic"). The Examiner states:

> Gangi, in view of Dardik, fairly suggests the claimed invention but not specifically force amplification. Nic, however, discloses that during injection of bone cement it may be necessary to amplify the force applied as the bone cement becomes less flowable (col. 10, I. 20-34). It would have been obvious to someone of ordinary skill in the art at the time of the invention to amplify the force in the modified invention of Gangi, in view of Dardik, if the bone cement becomes less flowable. Amplifying force using mechanical advantage was a known method at the time of the invention. Therefore, claim 51 would have been obvious because amplifying force using mechanical advantage was a part of the ordinary capabilities of one skill in the art.

As noted above, Dardik expressly provides no mechanical advantage and teaches that not providing mechanical advantage is advantageous in use. Gangi teaches something completely different, namely, the use of a pressure regulator rather than a hydraulic system that provides

mechanical advantage. A person of ordinary skill would not pursue this combination either because (1) Gangi has already solved the problem of injecting viscous cement by using a pressure regulator, or (2) Dardik expressly, in the hydraulic context, teaches against it.

CONCLUSION

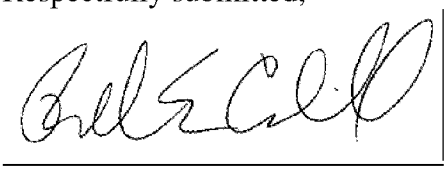
If the Examiner believes that an interview would facilitate the resolution of any outstanding issues, she is kindly requested to contact the undersigned.

In the event that a petition for an extension of time is required to be submitted at this time, Applicant hereby petitions under 37 CFR 1.136(a) for an extension of time for as many months as are required to ensure that the above-identified application does not become abandoned.

The Director is hereby authorized to charge any deficiency in the fees filed, asserted to be filed or which should have been filed herewith (or with any paper hereafter filed in this application by this firm) to our Deposit Account No. 141449, under Order No. 101896-890.

Dated: June 11, 2009

Respectfully submitted,



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